510(k) Summary of Safety and Effectiveness *

KANTERON DICOM STATION (KDS) (Software) Version 3.0

PICTURE ARCHIVING AND COMMUNICATIONS SYSTEM

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990:

Submitter's Information (per 21 CFR 807 92(a)(1)):

Trade Name: Kanteron DICOM Station (KDS)

Common Name: Picture Archiving Communications System

Classification Name: System, image processing, radiological

Product Code: LLZ

Predicate Device (21 CFR 807.92(a)(3):

FDA has classified the predicate device (K063470) as Class II; 21 CFR 892.2050, LLZ. I believe that Kanteron DICOM Station (KDS) device should have the same classification as the predicate device. Predicate device details are as follows:

Device Classification Name:	System, Image processing, Radiological
510(k) Number:	K063470
Regulation Number:	892.2050
Device Name:	Aycan Workstation OsiriX
Applicant:	Aycan Digitalsysteme GmbH
Classification Product Code:	LLZ
Decision date:	01/05/2007
Classification Advisory Committee:	Radiology

Applicable mandatory and voluntary standards:

Declaration of Conformity or certification statement to applicable voluntary standards that are cited for the device.

*** Any statement made in conjunction with this submission regarding substantial equivalence to any other product only relates to whether the product can be lawfully marketed without pre-market approval or reclassification and is not to be interpreted as an admission or used as evidence in patent infringement litigation. As the Commissioner of the FDA has indicated, ". . . a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act relates to the fact that the product can be lawfully marketed without pre-market approval or reclassification. The determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Fed. Reg. 42.520 et seg. (1977).**

See Declaration of Conformity (DICOM and JPEG standards) in Appendix 1 (Section 21).

DICOM (Digital Imaging and Communications in Medicine) - Developed by the American College of Radiology and the National Electrical Manufacturer's Association. Specifies the format for the communication of digital images between individual devices and over networks.

JPEG (Joint Photographic Experts Group) Standard - Specifies methods for the compression (reversible and irreversible) of digital medical images. References – ISO/IEC 10918-1 (1994-02) Digital Compression and Coding of Continuous-Tone Still Images (JPEG), G.K. Wallace, "The JPEG Still Picture Compression Standard", Communications of the ACM, Vol. 34, No. 4, April 1991.

Indications for Use (21 CFR 807 92(a)(5))

Indications for Use:

Kanteron DICOM Station (KDS) is a software device intended for viewing of images acquired from computer tomography (CT), magnetic resonance (MR), computed radiography (CR), digital radiography (DR), ultrasound (US), and other DICOM compliant medical imaging systems when installed on suitable commercial standard hardware.

Images and data can be captured, stored, communicated, processed and displayed within the system and or across computer networks at distributed locations.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretation.

For primary diagnosis, post process DICOM "for presentation" images must be used. Mammographic images must only be viewed with a monitor approved by the FDA for viewing mammographic images.

It is the User's responsibility to ensure monitor quality, ambient light conditions, and image compression ratios are consistent with clinical application.

The KDS is <u>not</u> intended for use as a preoperative surgical planning system and must not be used for this purpose.

Device Description: 21 CFR 807.92(a)(4)

The KDS provides services for review and post processing of diagnostic medical images and information. It conforms to the DICOM 3.0 standard to allow the sharing of medical information with other digital imaging systems. Kanteron DICOM Station (KDS) runs on Apple Mac OSX systems and provides high performance review, navigation and post processing functionality for multidimensional and multimodality images. Language files are separate from image software, allowing software to be provided in various languages.

Currently, the software is provided in English, Spanish, French, German, Japanese and Chinese.

KDS software facilitates viewing of images acquired from CT, MR, CR, DR, US, and other DICOM-compliant medical imaging systems when installed on suitable commercial standard hardware. Such images and data can be captured, stored, communicated, processed and displayed within the system and/or across computer networks at distributed locations. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretation. For primary diagnosis, post process DICOM "for presentation" images must be used. Mammographic images should only be viewed with a monitor approved by the FDA for viewing mammographic images. It is the User's responsibility to ensure monitor quality, ambient light conditions, and image compression ratios are consistent with clinical application.

Technical Characteristics and Principles of Operation:

Kanteron DICOM Station (KDS) is a software device that handles and manipulates digital medical images. The device does not contact the patient, nor does it control any life sustaining devices.

Technological Characteristics and Specifications: 21 CFR 807 92(a)(6)

Kanteron DICOM Station (KDS) is a software device that handles and manipulates digital medical images.

The device does not contact the patient, nor does it control any life sustaining devices. Prior to any medical decisions, a licensed medical practitioner reviews the output displays of the KDS system, providing ample opportunity for competent human intervention for the interpretation of images and information being displayed and printed.

Testing

As required by the hazard (risk) analysis, designated individuals performed all verification and validation activities and results demonstrated that the predetermined acceptance criteria were met. The System passed all testing criteria.

Kanteron uses standard irreversible compression techniques, laboratory data are not required.

Conclusion 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for the Kanteron Dicom Station contains adequate information and data to enable FDA/CDRH to determine substantial equivalence to the predicate device.

The submission contains the results of a hazard analysis and the “Level of Concern” for potential hazards has been classified as “Minor” (See Appendix 2 (Section 22)).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAR 19 2008

Ms. Monica Veytia
7195 SW 101 Street
MIAMI FL 33156-3247

Re: K073176
Trade/Device Name: KANTERON DICOM Station (KDS) Version 3.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 4, 2008
Received: March 12, 2008

Dear Ms. Veytia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K073176**

Device Name: KANTERON DICOM Station (KDS) Version 3.0

Indications for Use:

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The KDS is <u>not</u> intended for use as a preoperative surgical planning system and must not be used for this purpose.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K073176